REMARKS

Claims 34 to 38 remain in the application and stand rejected. Applicants are appreciative that the Examiner has withdrawn the claim rejections under Section 112, and the objections to the Specification. The present Amendment is submitted with a Request for Continued Examination.

References Raulerson, Consalvo and Cianci have been discussed and distinguished in previous responses.

Claim 34 is amended hereby to include the limitations that the first and second catheters are flexible (see paragraph [0048]), and that their distal end regions are implantable into and along vasculature of a patient. The claim is also amended to more specifically refer to implantation "of the first and second distal end regions of the catheter", to subcutaneous tunneling "of the first and second proximal end regions of the catheter", to "coextending, separated" lengths of proximal end portions, and to the portions co-extending distally from the hub. The limitations more clearly distinguish the claim from the prior art. Support is found at Figs 11 and 12 and paragraph [0036].

New claim 39 is entered, directed to the limitation that the hub is attachable to the catheters from beside them, and removable therefrom, after the catheter distal end portions have been implanted into a patient; see Figs. 11 and 12, and paragraph [0057]. New claim 40 is directed to the limitation that the hub is longitudinally translatable along the catheters after being attached thereto, as supported by paragraph [0036].

Claims 34 and 35 stand rejected under 35 USC §103(a) as being unpatentable over Consalvo (U.S. Patent No. 4,098,275) in view of either Cianci (U.S. Patent No. 4,149,539) or Raulerson (U.S. Patent No. 4,037,599). [It is believed that claims 36 to 38 also stand so rejected on the stated grounds, and will be treated as such in the present Response.]

Reference Consalvo sets forth a dual flow cannula set, but fails to disclose flexible catheters, and fails to disclose catheters that have distal end regions that are implantable into and along vasculature of a patient. Nor does the reference disclose catheters that are "separate from but adjacent to each other"; its two lumens are inherently separate flow passageways but are disposed within a common circular profile and do not qualify as equivalents to be "catheters [arguably] that are separate from but adjacent to each other." Nor does the reference disclose or suggest proximal end regions that may be subcutaneously tunneled. Further, there is no suggestion in the reference for such, since the disclosure is of a metal needle device with two lumens within a common circular profile at the Y-site. An important portion of the "hub" of Consalvo is a length

of Tygon tubing 14 that surrounds the needle at its Y-site; however, the tubing 14 cannot be attached to the needle after the distal end portion is "implanted" within the patient, nor can the tubing 14 be removed therefrom after the distal end portion is "implanted" within the patient.

Regarding the rejection of amended claim 34, reference Consalvo fails to disclose a hub placeable around coextending, separated proximal end regions, nor an implantable catheter assembly and fails to disclose that a practitioner assembles a hub to a catheter assembly at a site selected by the practitioner. The Y-site is permanently established at its location along the needle when at the factory. The tubing 14 of Consalvo cannot be connected to the needle after the needle distal end is "implanted" into the patient, nor can it be removed from the needle for the same reason (except by being destroyed). Reference Cianci fails to disclose two lengths of catheter tubing extending from distal end portions through the hub to proximal end portions proximally beyond the hub; only one tubing length extends distally from the hub, although two proximal tubing portions extend proximally therefrom. Reference Raulerson fails to disclose a releasably couplable hub securable to two catheter lengths by the practitioner. The combination of these references is not supported by a clear rationale supported by rational underpinnings, nor does the Office Action provide a basis for an artisan of routine skill to have a reasonable expectation of success to make the combination. Instead, the combination is the result of impermissible hindsight reasoning by the Examiner after having read Applicants' application. Therefore, Applicants respectfully traverse the combination and the rejection.

Claims 35 to 38 depend from claim 34, which is believed to patentably distinguish over the references, and therefore, claims 35 to 38 are believed patentable.

With respect to new claim 39, the tubing 14 is disclosed to be slid over the needle from the distal end thereof, while tubings 15,16 are slid from the proximal ends of the two diverging lumens. Regarding new claim 40, the "hub" of Consalvo cannot be longitudinally translatable along the needle since it is constrained to remain at the previously factory-fixed Y-site in order to remain an intact hub equivalent.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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